REMARKS

This is a response to the Office Action dated January 29, 2003. Claims 1-3, 5-8 and 17-19 are pending in this application. Claims 1-3 and 5-8 have been rejected by the Examiner. As noted above, Applicants have amended Claims 1, 2, 5, 6, and 8, and submitted New Claims 17-19. The amendments and New Claims 17-19 are fully supported by the written description and Figure 1. No new matter has been introduced into the application.

Response to Arguments

Applicants reiterate that the claimed invention has shown superior results which require a finding that the claimed invention was not obvious to one of ordinary skill in the art. It is well established in patent law that an applicant can rebut a *prima facie* case of obviousness by offering evidence of "secondary considerations." See, Graham v. John Deere Co., 383 U.S. 1, 17-18 (1965). Rebuttal evidence may include evidence that the claimed invention yields unexpectedly improved properties or properties not present in the prior art. See, In re Dillon, 919 F.2d 688, 692-93 (Fed. Cir. 1990). As noted in the Response dated January 17, 2003, Applicants' invention has addressed some of the long-felt problems associated with **coating stents**. In particular, Applicants have clearly demonstrated that the claimed invention yields improved properties which alleviate problems such as the formation of polymer "cob webs" between the stent struts, excessive gathering of clumps or "pool webs" of coating on the surface of the stent struts, and lack of uniformity of the coating.

The Examiner has stated that the Applicants' argument is not persuasive because the prior art references have confirmed that a stent coating can be "made more uniform and smooth via heating" and that the prior art references have showed "improved uniformity in thickness of a coating composition when the coating composition is heated during application." Applicants respectfully disagree. First and foremost, none of the prior art references even suggest an

apparatus for coating a stent. Leidner et al. is merely directed to a method "co-spraying both a water soluble and water insoluble fibrous component onto a mold **to form the prosthesis precursor**" (abstract) (emphasis added). Moreover, the Blackington and the Kawata et al. references do not even provide a hint that their apparatuses could be used to coat a medical device, let alone a stent. Specifically, Blackinton is merely directed to a spray gun apparatus for painting vertical surfaces, and Kawata et al. only discloses an apparatus for coating a semiconductor wafer, such as a resist coater. None of the prior art references, therefore, would suggest an apparatus for producing a stent coating that can be "made more uniform and smooth via heating."

Furthermore, Applicants respectfully disagree with the Examiner's position that the prior art references address the problems of coating stents, and in particular, the Examiner's characterization of the Leidner et al. reference. Specifically, the Examiner has stated that Leidner et al. has "solved the problem of lack of uniformity of coating in stent manufacture." However, Leidner et al., nor do any of the other prior art references, provide any objective evidence that they have solved the problems of "cob web" formation between stent struts, nor have they solved the problem of excessive gathering of clumps or "pool webs" of coating on the surface of the stent struts. Leidner et al., for instance, merely propose that "coating 36 may be heated to a temperature close to, more preferably slightly above, the glass transition temperature of the material(s) constituting coating 36 so that the material of coating 36 at least partially melts **to provide a smooth, even, uniform coatable surface upon which to form prosthesis 9**" (col. 14, lines 30-38) (emphasis added).

Because Applicants have clearly demonstrated that the claimed invention has shown superior results, Applicants respectfully request the Examiner to reconsider the finding of obviousness.

Claim Rejections – 35 USC § 103

A. **Leidner et al. In View of Kawata et al.**

Claims 1-3 and 5-8 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Leidner et al. (USPN 6,056,993) in view of Kawata et al. (USPN 4,932,353). Leidner et al. is directed to "[a] porous, tubular synthetic prosthesis, prosthesis precursor, and methods of producing the same . . . . Specifically the method involves co-spraying both a water soluble and water insoluble fibrous component **onto a mold to form the prosthesis precursor**" (abstract) (emphasis added). Leidner et al. disclose that as part of the method of forming the prosthesis "[t]o help make coating 36 more uniform and smooth, coating 36 **may be heated prior to electrostatic spraying operations**" (col. 14, lines 30-32) (emphasis added).

Kawata et al. is directed to "[a] chemical coating apparatus [that] has **a heat exchanger disposed along a pipe** for transporting a chemical for adjusting the temperature of the chemical to a predetermined value through a corresponding flow of constant-temperature water" (abstract) (emphasis added). In particular, Kawata et al. is directed to "a resist coater which is used to apply a resist on the surface of a semiconductor wafer during the process of manufacturing semiconductor devices" (col. 1, lines 14-17). Kawata et al. disclose "[i]t is an object of the present invention to provide a chemical coating apparatus, such as a resist coater, which is capable of adjusting the temperature of the chemical, such as the resist, along its path of travel" (col. 1, lines 47-51).

To establish *prima facie* obviousness, **all of the claimed limitations** must be taught or suggested in the references cited. In re Royka, 490 F.2d 981 (CCPA 1974). Leidner et al. and Kawata et al., alone or in combination, fail to teach or suggest an applicator that comprises

> a body portion;
> a nozzle, including an orifice, extending from the body portion; and
> **a temperature controller coupled to the nozzle**, the temperature controller being coupled to the nozzle **in close proximity to the orifice so as to change the temperature of a coating substance as it passes through the orifice, wherein the**

temperature controller is sized so as to change the temperature of the coating substance at a concentrated area of the nozzle so as to prevent exposure of the coating substance to the change in temperature along the entire length of the body portion

as recited by amended Claim 1. Leidner et al. merely disclose that the coating "may be heated prior to electrostatic spraying operations" (col. 14, lines 31-32), or that "[m]andrel 12 and prosthesis 9 may be heated during winding operations, if desired. For example, a 250 watt IR lamp can be placed about 190 mm **away from mandrel 12** for this purpose" (col. 12, lines 28-31) (emphasis added). Also, Kawata et al. disclose an apparatus with heat exchangers, Kawata et al. fail to teach or suggest that the heat exchangers are "**a temperature controller coupled to the nozzle**, the temperature controller being coupled to the nozzle **in close proximity to the orifice so as to change the temperature of a coating substance as it passes through the orifice"** as recited by Claim 1. Moreover, Kawata et al. fail to disclose that, "**the temperature controller is sized so as to change the temperature of the coating substance at a concentrated area of the nozzle**." Instead, the heat exchangers of Kawata et al. are positioned **along the entire transport path** of the resist liquid **up to a point shy of the nozzle**. This relationship is best shown in Figure 3. Because the heat exchangers of Kawata et al. are disposed along the entire transport path of the resist liquid, but not at the nozzle, the heat exchangers cannot adjust the temperature of the resist liquid "**at a concentrated area of the nozzle so as to prevent exposure of the coating substance to the change in temperature along the entire length of the body portion**" as recited in Claim 1. Accordingly, Claim 1 is allowable over Leidner et al. in view of Kawata et al. Claims 2 and 3 depend on Claim 1, and are allowable for at least the same reason.

Additionally, Leidner et al. and Kawata et al., alone or in combination, fail to teach or suggest all of the claimed limitations of amended Claim 5. In particular, the references fail to teach or suggest an apparatus that comprises

(a) an applicator for spraying a composition at the stent; and

(b) a temperature controller connected to the applicator and **configured to adjust the temperature of the composition to a temperature other than ambient temperature in a concentrated area** during the application process **to prevent prolonged thermal exposure of the composition**.

As noted above, Leidner et al. merely disclose that the coating "may be heated prior to electrostatic spraying operations" (col. 14, lines 31-32) or that the mandrel and prosthesis can be heated **from a distance** (see, col. 12, lines 28-31). Also, Kawata et al. fail to teach or suggest "a temperature controller connected to the applicator and **configured to adjust the temperature of the composition to a temperature other than ambient temperature in a concentrated area**" as recited by Claim 5. As a result, the heat exchangers of Kawata et al. would be unable to adjust the temperature of the liquid "**to prevent prolonged thermal exposure of the composition**." Accordingly, Claim 5 is allowable over Leidner et al. in view of Kawata et al. Claims 6-8 depend on Claim 5, and are allowable for at least the same reason.

In addition, Applicants respectfully submit that the Examiner has failed to establish a *prima facie* case of obviousness because there would have been no suggestion or motivation to modify Leidner et al. with the teachings of Kawata et al. in order to make the claimed invention. There are three possible sources for a motivation to combine references: "the nature of the problem to be solved, the teachings of the prior art, and the knowledge of persons of ordinary skill in the art." In re Rouffet, 149 F.3d 1350, 1357 (Fed. Cir. 1998). However, the mere fact that a prior art reference can be modified does not make the modification obvious unless the prior art also suggests the desirability of the modification. See In re Gordon, 733 F.2d 900, 902 (Fed. Cir. 1984). Moreover, the suggestion or motivation to make the claimed combination **must be found in the prior art, and not based on applicant's disclosure**. See In re Vaeck, 947 F.2d 488, 493 (Fed. Cir. 1991).

First, there was no evident desirability to modify the Leidner et al. reference based on the nature of the problems to be solved. Some of the relevant problems include uneven coatings on

stents, the formation of "cob webs" and "pool webs" on the surface of stent struts, and prolonged thermal exposure of a composition that can lead to the degradation of components of the composition such as thermally sensitive drugs. Neither Leidner et al., nor Kawata et al. provide any suggestion that that they were concerned about the problems of "cob web" formation between stent struts, excessive gathering of clumps or "pool webs" of coating on the surface of the stent struts, or the prolonged thermal exposure of a coating substance.

Secondly, the disclosures of the prior art references do not provide any suggestion that it would have been desirable to combine the references to make the claimed invention because the references are directed to two entirely different arts. The only commonality is that the references are directed to coating substrates. Applicants respectfully submit that one of ordinary skill in the art of coating stents would not have had any motivation to look beyond the technology disclosed in Leidner et al. In particular, there is no suggestion or hint in the prior art references that one of ordinary skill in the art would have looked to the art of applying a resist to a semiconductor wafer to produce the claimed invention. Thus, it appears the Examiner has combined two completely disparate references without any hint that one of ordinary skill in art would have any motivation to do so.

Furthermore, the prior art references teach away from a combination to make the claimed invention. Leidner et al. disclose that as part of the method of forming the prosthesis "[t]o help make coating 36 more uniform and smooth, coating 36 **may be heated prior to electrostatic spraying operations**. Preferably, coating 36 may be heated to a temperature close to, more preferably slightly above, the glass transition temperature of the material(s) constituting coating 36 **so that the material of coating 36 at least partially melts** to provide a smooth, even, uniform coatable surface upon which to form prosthesis 9" (col. 14, lines 30-38) (emphasis added). The above quotation from Leidner et al. indicates that Leidner et al. teach that the coating solution should be heated to a high temperature (e.g., the glass transition temperature of

the material). As a result, Leidner et al. actually teach away from an apparatus that is configured to **prevent prolonged thermal exposure** of a coating substance as the coating substance is being applied to a stent. Therefore, one of ordinary skill in the art would not have had any motivation to modify the Leidner et al. reference and as such, the Examiner has failed to establish a *prima facie* case of obviousness.

B. **Leidner et al. In View of Blackinton**

Claims 1-3 and 5-8 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Leidner et al. in view of Blackinton (USPN 4,132,357). Blackinton is directed to "[a]n apparatus and method for the spray application of solvent-thinned coating compositions whereby optimum coverage of a substrate with a liquid film is consistently achieved without incurring sagging, run-off or surface irregularities" (abstract). Blackington discloses that for the apparatus,

> The butt of the hand grip 12 is connected by a hose 18 to a supply of pressurized atomizing air such as a blower 20, which in accordance with a variation of the process may further include **a heat exchanger 22 for controlling the temperature of the atomizing air supplied to the spray gun**. The forward end portion of the spray gun is connected by means of a conduit 24 to a supply tank containing a solvent-thinned liquid paint 26 and further includes a pump 28 and **a heat exchanger 30 as an optional element for controlling the temperature of the liquid paint supplied to the spray gun**. Alternatively, the conduit 24 may be connected to a supply tank of paint which is withdrawn by aspiration or suction therefrom

(col. 5, lines 1-14) (emphasis added).

Applicants respectfully submit that Leidner et al. and Blackinton, alone or in combination, fail to teach or suggest all of the claimed limitations of the claimed invention. In particular, the references fail to teach or suggest an applicator that comprises

> a body portion;
> a nozzle, including an orifice, extending from the body portion; and
> **a temperature controller coupled to the nozzle**, the temperature controller being coupled to the nozzle **in close proximity to the orifice so as to change the temperature of a coating substance as it passes through the orifice, wherein the temperature controller is sized so as to change the temperature of the coating substance at a concentrated area of the nozzle so as to prevent exposure of the coating substance to the change in temperature along the entire length of the body portion**

as recited by amended Claim 1. As noted above, Leidner et al. merely disclose that the coating "may be heated prior to electrostatic spraying operations" (col. 14, lines 31-32) or that the mandrel and prosthesis can be heated **from a distance** (see, col. 12, lines 28-31). Also, even though Blackinton discloses heat exchangers "for controlling the temperature of the atomizing air supplied to the spray gun" and "for controlling the temperature of the liquid paint supplied to the spray gun," Blackinton clearly fails to disclose that the heat exchangers are "**coupled to the nozzle in close proximity to the orifice** so as to change the temperature of a coating substance as it passes through the orifice," or that "**the temperature controller is sized so as to change the temperature of the coating substance at a concentrated area of the nozzle.**" Therefore, the heat exchangers of Blackinton can not "**prevent exposure of the coating substance to the change in temperature along the entire length of the body portion**" as recited by amended Claim 1. Accordingly, Claim 1 is allowable over Leidner et al. in view of Blackinton. Claims 2 and 3 depend on Claim 1, and are allowable for at least the same reason.

The references also fail to teach or suggest all of the claimed limitations of amended Claim 5, such as an apparatus that comprises "a temperature controller **connected to the applicator** and configured to adjust the temperature of the composition to a temperature other than ambient temperature **in a concentrated area** during the application process **to prevent prolonged thermal exposure of the composition.**" In particular, Leidner et al. merely disclose that the coating may be heated, and Blackinton merely discloses heat exchangers "for controlling the temperature of the atomizing air supplied to the spray gun" and "for controlling the temperature of the liquid paint supplied to the spray gun." Neither reference discloses an apparatus that can prevent prolonged thermal exposure of a coating composition. Accordingly, Claim 5 is allowable over Leidner et al. in view of Blackinton. Claims 6-8 depend on Claim 5, and are allowable for at least the same reason.

In addition, Applicants respectfully submit that the Examiner has failed to establish a *prima facie* case of obviousness because there would have been no suggestion or motivation to modify Leidner et al. with the teachings of Blackinton in order to make the claimed invention. As noted above, there was no evident desirability to modify the Leidner et al. reference based on the nature of the problems to be solved. Neither Leidner et al., nor Blackinton provide any suggestion that that they were concerned about the problems of "cob web" formation between stent struts, excessive gathering of clumps or "pool webs" of coating on the surface of the stent struts, or the prolonged thermal exposure of a coating substance.

Moreover, the disclosure of the prior art references do not provide any suggestion that it would have been desirable to combine the references to make the claimed invention because the references are directed to two entirely different arts. Applicants respectfully submit that one of ordinary skill in the art of coating stents would not have had any motivation to look beyond the technology disclosed in Leidner et al. In particular, there is no suggestion or hint in the prior art references that one of ordinary skill in the art would have looked to the art of spray guns as disclosed in Blackinton to produce the claimed invention.

The prior art references also teach away from a combination to make the claimed invention. As discussed above, Leidner et al. teach that the coating solution should be heated to a high temperature (e.g., the glass transition temperature of the material). As a result, Leidner et al. teach away from an apparatus that is configured to **prevent prolonged thermal exposure** of a coating substance as the coating substance is being applied to a stent. Therefore, one of ordinary skill in the art would not have had any motivation to modify the Leidner et al. reference, and as such, the Examiner has failed to establish a *prima facie* case of obviousness.

CONCLUSION

Claims 1-3, 5-8 and 17-19 are pending in this application. Examination and allowance of the claims are respectfully requested. If the Examiner has any questions or concerns, the Examiner is invited to telephone the undersigned attorney at (415) 954-0345.

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Respectfully submitted,

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Version With Markings To Show Changes Made

IN THE CLAIMS

Please amend the Claims as indicated below. The Italicized claims have not been amended in this Response and are provided for the Examiner's convenience.

1. (Twice Amended) An applicator for applying a coating substance to a stent, comprising ~~a nozzle and a temperature controller in thermal communication with the nozzle for adjusting the temperature of a coating substance during an application of the coating substance to the stent~~

a body portion;

a nozzle, including an orifice, extending from the body portion; and

a temperature controller coupled to the nozzle, the temperature controller being coupled to the nozzle in close proximity to the orifice so as to change the temperature of a coating substance as it passes through the orifice, wherein the temperature controller is sized so as to change the temperature of the coating substance at a concentrated area of the nozzle so as to prevent exposure of the coating substance to the change in temperature along the entire length of the body portion.

2. (Amended) The applicator of Claim 1, wherein the temperature controller circumscribes ~~the nozzle and is position in close proximity to an orifice~~**a portion** of the nozzle ~~through which the coating substance is applied~~.

3. *The applicator of Claim 1, wherein the coating substance includes a polymer dissolved in a solvent and optionally a therapeutic substance added thereto.*

Claim 4 was canceled without prejudice in the Response dated January 17, 2003.

5. (Amended) An apparatus for applying a composition to a stent **during a coating process**, comprising:

(a) an applicator for spraying a composition at the stent; and

(b) a temperature controller connected to the applicator ~~for adjusting~~**and configured to adjust** the temperature of the composition to a temperature other than ambient temperature **in a concentrated area during the application process to prevent prolonged thermal exposure of the composition**.

6. (Amended) The apparatus of Claim 5, wherein the applicator comprises a body extending into a nozzle, such that the temperature controller is positioned in close proximity to **an orifice of** the nozzle **through which the coating substance is sprayed, and wherein the temperature controller does not extend along the entire length of the body of the applicator to prevent prolonged exposure of composition to the temperature controller**.

7. *The apparatus of Claim 5, wherein the applicator is an air-assisted internal or external mixing atomizer.*

8. (Twice Amended) The apparatus of Claim 5, additionally including a temperature modulator in communication with the temperature controller for maintaining the temperature of the composition at a constant level during ~~an~~**the** application process.

Claims 9-16 were canceled without prejudice in the Response dated January 17, 2003.

Please add the following New Claims:

17. (New) The applicator of Claim 1, wherein the temperature controller is a heat source.

18. (New) The apparatus of Claim 5, wherein the temperature controller is a heat source.

19. (New) The apparatus of Claim 6, wherein the temperature controller circumscribes a portion of the periphery of the orifice.